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| EXAMINER |
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SWIGER III, JAMES L

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| ART UNIT | PAPER NUMBER |
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3775

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| NOTIFICATION DATE | DELIVERY MODE |
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10/06/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
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| | | | |
|------------------------------|--------------------------------------|------------------------------------|--|
| Office Action Summary | Application No. 10/501,004 | Applicant(s) GRAF ET AL. | |
| | Examiner JAMES L. SWIGER | Art Unit 3775 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 3, 11-15, 18-26, 31 and 32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-7, 16 and 17 is/are rejected.
- 7) ☒ Claim(s) 8-10 and 27-30 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 7/8/2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Invention I (directed to claims 1-24 and 26-32), drawn to a system, and Species I of the orientation device (directed to claims 1, 4-15, 19-32) and Species II of the manipulation joint heat (directed to claim 16), of the orientation device in the reply filed on 5/26/2009 is acknowledged.

In regards to the above election, it can best be ascertained that the relevant claims to the elected embodiments are: 1-10, 16-17, 27-30.

Claims 3, 11-15, 18-26, 31-32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 5/26/2009.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2, 4-10, 16-17, 27-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim, line 6 applicant refers to a "cutting head and/or an impact instrument." Use of and/or renders the claim indefinite.

Appropriate action is required.

Claim 2 recites the limitation "manipulation joint head" in line 2. There is insufficient antecedent basis for this limitation in the claim. Applicant has previously only claimed a "manipulation joint."

Appropriate action is required.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant uses the term "latter" in line 4. Since there are several elements in this claim, it is unclear as to what exactly "so that the latter" implies.

Appropriate action is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, 4-5, 7 rejected under 35 U.S.C. 103(a) as being unpatentable over Mosseri (US Patent 6,231,611) in view of Oh (US Patent 4,475,549). Mosseri discloses an accessory device for implantation of a hip joint comprising manipulation cup (7b, fig. 1) connected to a manipulation joint a means to orient a manipulation cup (7) in an acetabulum area (shown, see drawings), and wherein the entire device works to permit a bone milling device or cutter (6 or 12) have proper alignment to prepare a site for installation of a prosthesis cup (5). The accessory device (fig. 1) further has a guide rod (4) that has a threaded distal end (4b), and is fully capable of being screwed in to bone

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and assists in orienting the device so that the manipulation cup can be maneuvered.

The end of the accessory forms a template (2a) in which a guide rod is fastened and which can then orient a cutting drive axle, such as shown in Fig. 6, 12.

Mosseri discloses the claimed invention except for a manipulation joint that also comprises a shoulder and a cup that has an opening to allow a bone milling instrument. Oh discloses an accessory instrument that has a joint (13) with a shoulder (25) and a cup with an opening (29). These instruments could modify Mosseri at the end 7b/7c, and allow full polyaxial motion for proper positioning of the device, and have certain bounds on this movement provided by the shoulder, and still allow a device access through the opening. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Mosseri having at least a manipulation joint that also comprises a shoulder and a cup that has an opening in view of Oh, so that the device may be properly positioned in addition to instruments having access.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mosseri in view of Oh as applied to claim 4 above, and further in view of Kenna (US patent 4,528,980). Mosseri in view of Oh discloses the claimed invention except for a component that connects the manipulation cup via a guide rod via a bore. Kenna discloses a component with a bore (Fig. 10, 52, and bore shown in Fig. 9) that allows connection of a manipulation cup via a rod and bore. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Mosseri in view of Oh, having at least a component connecting a manipulation cup

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via a bore in further view of Kenna, so that the components can maintain their proper angles while providing a realistically sized apparatus for a surgeon to use.

Claims 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mosseri in view of Oh as applied to claim 1 above, and further in view of Sarin et al. (US Publication 2003/0153829). Mosseri in view of Oh discloses the claimed invention except for the use of an optical-based detection means to orient the manipulation cup. Sarin discloses a system that provides an optical result useful to a surgeon. The feedback provided by the device would allow for the surgeon to properly place the accessory. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Mosseri in view of Oh having at least an optical based detection means in view of Sarin to have more precision in placement of the device.

Allowable Subject Matter

Claims 8-10 and 27-30 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES L. SWIGER whose telephone number is (571)272-5557. The examiner can normally be reached on Monday-Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached on 571-272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JAMES L. SWIGER/
Examiner, Art Unit 3775